American Hospital Association™
Advancing Health in America

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March 13, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

Re: CMS 0057-P, Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-facilitated Exchanges, Merit-based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program

Dear Administrator Brooks-LaSure:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations and our clinician partners — including more than 270,000 affiliated physicians, two million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Advancing Interoperability and Improving Prior Authorization Processes proposed rule.

The AHA commends the Centers for Medicare & Medicaid Services (CMS) for taking action to remove inappropriate barriers to patient care by streamlining the prior authorization processes for the impacted health plans and providers. While prior authorization can be a tool to help ensure patients receive coverage for their care, the practice too often is used in a manner that leads to dangerous delays in treatment, clinician burnout and waste in the health care system. The proposed rule is a welcome step toward helping patients get timely access to care and clinicians focus their limited time on patient care rather than paperwork. However, to truly realize these benefits, we urge CMS to ensure a baseline level of enforcement and oversight. In addition, while hospitals and health systems appreciate CMS' effort to improve the electronic exchange of care data to reduce provider burden and streamline prior authorization processes, we

urge CMS to ensure that any electronic standards are adequately tested and vetted prior to mandated adoption.

Our detailed comments follow.

BACKGROUND

According to America's Health Insurance Plans (AHIP), prior authorization is implemented by health plans "to help ensure patients receive optimal care based on well-established evidence of efficacy and safety, while providing benefit to the individual patient."[1] Philosophically, we agree with these laudable goals, and, indeed, some health plans use prior authorization in ways that accomplish them. However, many health plans apply prior authorization requirements in ways that create dangerous delays in care, contribute to clinician burnout and drive-up costs for the health care system.

Inefficient or misapplied prior authorization can negatively impact quality of care. According to a 2021 American Medical Association survey of more than 1,000 physicians, 91% of respondents indicated that prior authorization "had a significant or somewhat negative clinical impact, with 34% reporting that prior authorization had led to a serious adverse event such as a death, hospitalization, disability or permanent bodily damage, or other life-threatening event for a patient in their care."[2] The federal government also has acknowledged the risk of delays in care caused by prior authorization requirements, which is why it urged health plans to ease such requirements during the COVID-19 public health emergency, stating "new guidance for individual and small group health plans encourages issuers to utilize flexibilities related to utilization management processes, as permitted by state law, to ensure that staff at hospitals, clinics, and pharmacies can focus on care delivery and ensure that patients do not experience care delays."[3]

Prior authorization puts a heavy burden on clinicians and contributes to workforce burnout. According to the National Academies of Medicine, "Among clinicians, burnout is associated with job demands related to workload, time pressure, and work inefficiencies, such as burdensome administrative processes which divert clinicians' attention away from patients and detract from patient care."[4]

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[1] America's Health Insurance Plans, "Frequently Asked Questions: Medical Management and Prior Authorization," Available at: https://www.ahip.org/documents/Prior-Authorization-FAQs.pdf
[2] American Medical Association, "2021 AMA Prior Authorization (PA) Physician Survey," Available at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf
[3] Centers for Medicare & Medicaid Services, "CMS News Alert April 23, 2020," Available at: https://www.cms.gov/newsroom/press-releases/cms-news-alert-april-23-2020
[4] National Academies of Medicine, "Taking Action against Clinician Burnout: A Systems Approach to Professional Well-Being," Available at: https://nam.edu/wp-content/uploads/2019/10/CR-report-highlights-brief-final.pdf

One of the most frustrating aspects of prior authorization for providers is the variation in submission processes. Plans vary widely on accepted methods of prior authorization requests and supporting documentation submission. While some plans accept electronic means, the most common method remains using fax machines and contacting call centers, with regular hold times of 20 to 30 minutes. In addition, plans offering electronic methods of submission most commonly use proprietary plan portals, which require a significant amount of time spent logging into a system, extracting data from the provider's clinical system and completing idiosyncratic plan requirements, thereby reducing the administrative efficiencies of the process. For each plan, providers and their staff must ensure they are following the correct rules and processes, which may change from one request to the next. Inevitably, providers commit inadvertent errors that result in denials that must be reprocessed or appealed.

The use of standardized electronic prior authorization transactions has the potential to save patients, providers and utilization review entities significant time and resources and can speed up the care delivery process. Many of CMS' proposals will improve communication and transparency, provide patients continuity of care protections and advance process efficiencies. **We applaud CMS for taking these important steps to require plans, including Medicare Advantage (MA) plans, to implement these critical prior authorization and electronic data exchange reforms.**

SCOPE OF THE PROPOSED RULE

Inclusion of Medicare Advantage

The AHA applauds CMS' proposal to require MA plans to adhere to the rule. As CMS indicates, providers benefit from standardization of processes across various payers. Currently, differing protocols dependent on a patient's insurance plan requires the implementation of multiple workflows for completing the same process, thereby increasing administrative costs and contributing to provider burnout. Hence, including MA, which will significantly increase the volume of impacted patients, will help ease provider adoption and implementation.

The regulation establishes that impacted patients will experience improved efficiencies in the manner in which they receive care by reduced timelines and procedural improvements. The inclusion of MA plans in this rule meaningfully increases the number of patients who will benefit from those efficiencies, as more than 28 million Medicare beneficiaries enrolled in MA plans as of 2022, accounting for 48% of the total Medicare population and 55% of total federal Medicare spending. The Congressional Budget Office (CBO) estimates that the share of Medicare beneficiaries enrolled in MA plans will increase to 61% by 2032.[5] Accordingly, including MA plans in the proposed rule

[5] Kaiser Family Foundation, "Medicare Advantage in 2022: Enrollment Update and Key Trends," Available at: https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-enrollment-update-and-key-trends/

greatly expands the number of patients and providers who stand to benefit from the rule's process improvements.

Importantly, MA plans have an established history of inappropriately utilizing prior authorization to deny medically necessary treatment for patients. In 2022, 99% of MA enrollees were enrolled in a plan that required prior authorization of some services.[6] Data from 2021 shows that more than 35 million prior authorization requests were submitted to MA plans on behalf of MA enrollees.[7] Moreover, according to a 2022 report by the Department of Health and Human Services (HHS) Office of Inspector General (OIG), MA organizations denied 13% of prior authorization requests that met Medicare coverage rules.[8] Additionally, a 2018 HHS-OIG report found that MA organizations overturned 75% of prior authorization denials that were appealed between 2014 and 2016.[9] This elucidation of such widespread inappropriate denial of necessary care establishes that MA plan prior authorization practices are in dire need of reform, and their inclusion in this proposed rule is a welcome step toward holding MA plans accountable to permitting required and necessary patient care.

The AHA recognizes that, though some duplication and variation in insurer processes is inevitable, standardized electronic prior authorization transactions has the potential to save patients, providers and utilization review entities significant time and resources and can speed up the care delivery process. Inefficient prior authorization processes have routinely caused administrative burden for providers and inappropriate care delays for patients, and providers are eager to adopt more streamlined approaches. As a result, we have consistently advocated for the establishment of an efficient, standardized electronic method of processing prior authorizations across the various payers with whom they interact. In keeping with this long-held position, we believe that the best method of getting providers to adopt the technology is to increase the number of health plans that are required to utilize the proposed electronic standards. We thank CMS for sharing this sentiment, and **we urge CMS to finalize the proposal to include MA plans. Additionally, recognizing the importance of process standardization across payers and plans, we encourage CMS to explore adopting these policies under the Health Insurance Portability and Accountability Act (HIPAA) regulation**

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[6] Kaiser Family Foundation, "Over 35 Million Prior Authorization Requests were Submitted to Medicare Advantage Plans in 2021," Available at: https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021/

[7] Kaiser Family Foundation, "Over 35 Million Prior Authorization Requests were Submitted to Medicare Advantage Plans in 2021," Available at: https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021/

[8] U.S. Department of Health and Human Services Office of Inspector General. "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care," Available at: https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf

[9] U.S. Department of Health and Human Services Office of Inspector General. "Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns about Service and Payment Denials," Available at: https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf

and making meaningful strides to leverage available technology to reduce administrative burden throughout the industry.

Exclusion of Drugs Covered under a Medical Benefit

Patients and providers have a critical need for accurate and up-to-date information about the status of their prior authorizations for drug therapies. While the AHA agrees with CMS that the processes and standards for the prior authorization of drugs often differ from that of medical items and services, there is a distinction between the prior authorization processes for drugs covered under a patient's pharmacy benefit and drugs covered under a patient's medical benefit. While the electronic prior authorization process for the pharmacy benefit follows the NCPDP SCRIPT standard, this standard does not apply to drugs covered by a medical benefit. Today, prior authorization for drugs covered under the medical benefit generally follow the payers' process for all medical benefits. By excluding drugs from this regulation, the agency is creating a scenario where drugs covered under the medical benefit fall through a loophole.

The proposed exclusion of drugs covered under the medical benefit is especially troubling because health plans typically cover physician-administered drugs and specialty drugs through a patient's medical benefit, including specialty drugs. Common specialty drugs include chemotherapy, biologics and immunosuppressants. Due to the complexity and significant costs associated with these drugs, insurers almost uniformly require prior authorization for their use.[10, 11]

The application of prior authorization to specialty drugs can be particularly detrimental to patients who rely on these medications to manage and treat complex disease. For example, a recent study focusing on prior authorization of infusion medication to treat a rheumatologic condition found that prior authorization requirements are associated with treatment delays and can result in serious negative consequences for patients' health.[12] Of the 225 rheumatology patient medical records recommending a medication administered via infusion reviewed in the study, 71% of the patients had a health plan policy requiring prior authorization before the drug could be administered, with these patients forced to wait longer to start receiving infusions and experiencing poorer outcomes. In the meantime, patients who had to wait for prior authorization approval

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[10] Optum, "Specialty Drugs and Prior Authorizations," Available at: https://www.optum.com/business/insights/pharmacy-care-services/page.hub.specialty-drugs-prior-authorizations.html - :~:text=Specialty drugs typically require a,provider on the medical benefit
[11] United Healthcare, "Clinical Pharmacy and Specialty Drug Prior Authorization Programs," Available at: https://www.uhcprovider.com/en/prior-auth-advance-notification/prior-auth-specialty-drugs.html
[12] Zachary S. Wallace, et al, "Treatment Delays Associated with Prior Authorizations for Infusible Medications: A Cohort Study," Available at: https://doi.org/10.1002/acr.24062

were more likely to be treated with a steroid, which can have serious side-effects, to alleviate rheumatic symptoms.

Adding to the concern is that specialty drugs often require special handling, storage and administration requirements, making any delays caused by prior authorization particularly disruptive and potentially dangerous for patients. Further, the negative impacts of prior authorization on specialty drugs are only increasing as the specialty drug market continues to grow. In 2021, specialty drugs accounted for 50% of total drug spending.[13]

Moreover, to help patients select a health plan that is right for them, it is imperative that potential enrollees have access to information detailing all the services for which an insurer requires prior authorization. In the case of specialty pharmacy coverage, patients also should be provided information about medications that require step therapy or white bagging, site of service exclusions for medication administration, or medications placed in a tiered or preferred formulary structure which may impact patient cost-sharing, especially as these utilization management techniques are operationalized using the prior authorization process. Particularly for patients with chronic or recurring conditions, knowledge of whether a necessary therapy will be subject to prior authorization or other utilization management review is critical.

We believe including drugs covered under the medical benefit in the Prior Authorization Requirements, Documentation and Decision (PARDD) API is technologically feasible. Currently, the Coverage Requirements Discovery (CRD) Implementation Guide (IG) supports the MedicationRequest resource, and the Prior Authorization Support (PAS) IG value set contains Healthcare Common Procedure Coding System (HCPCS) J-codes used by providers for physician-administered drugs.[14] Therefore, plans implementing the regulation already will have the functionality necessary to address drugs covered under the medical benefit. For patients to fully realize the transparency and process improvements from the PARDD API, we urge CMS to expand the scope of health care items and services to include drugs provided under a patient's medical benefit.

IMPROVING PRIOR AUTHORIZATION PROCESSES

Prior authorization policies burden providers and divert valuable resources from patient care. For example, one 17-hospital system spends $11 million annually simply

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[13] Health and Human Services Office of Science and Data Policy, "Trends in Prescription Drug Spending, 2016 – 2021," Available at: https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf

[14] HL7, Da Vinci Prior Authorization Support (PAS), Available at: https://build.fhir.org/ig/HL7/davinci-pas/ValueSet-X12278RequestedServiceType.html

complying with health plan prior authorization requirements, and a single 355 bed psychiatric facility needs 24 full-time staff members to deal with prior authorizations. Another large, national system spends $15 million per month in administrative costs associated with managing health plan contracts, including two to three full-time staff members that do nothing but monitor plan bulletins for changes to the rules.[15] Additionally, physicians report that they and their staff spend about two days per week completing prior authorizations, and 88% of physicians describe the burden associated with prior authorization as high or extremely high.[16] **In light of these burdensome realities, the AHA strongly supports prior authorization reform, including adoption of electronic prior authorization processes that have the ability to streamline the arduous process to improve patient care and reduce provider burnout.**

Prior Authorization Requirements, Documentation and Decision API

The AHA is supportive of technological advancements shown to improve safety, quality and efficiency of care for patients. The proposed rule calls for the creation of FHIR-based APIs to facilitate the exchange of information necessary to streamline prior authorization processes directly from a provider's electronic health record (EHR) system. We strongly support this proposal, as the AHA has long advocated for the creation of electronic prior authorization standards that integrate with provider clinical information systems to eliminate time spent transposing clinical data from one system to another.

The AHA agrees with CMS' proposal to require the use of FHIR standards found in the Office of the National Coordinator for Health Information Technology's (ONC) certification program and the functional requirement of PARDD APIs to closely align with the named Da Vinci IGs. This would help ensure close alignment between payers and EHR vendors. Variance in API usage and how the FHIR transaction is implemented could require significant added vendor services to navigate, which would increase provider costs, thus undermining savings and process simplification. Streamlining API usage would allow for providers to access and share prior authorization data with plans more efficiently to reduce burden and enhance patient care. Moreover, we encourage such API solutions to incorporate the ability to alert providers who are not subject to prior authorization (e.g., due to cost-sharing arrangements, "gold card" processes, etc.) in real-time and do not need to navigate any of the processes.

Additional Testing and Analysis

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[15] Examples provided by an AHA member hospitals.
[16] American Medical Association. "2021 AMA Prior Authorization (PA) Physician Survey." Available at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

The Da Vinci IGs discussed in this proposed rule have the potential to meaningfully support the needed transition to electronic prior authorization. Nonetheless, the incorporation of new technology can be an extremely resource-intensive process for hospitals and other providers, requiring systematic updates, testing, personnel education and training, workflow adjustments and potential policy changes all while performing their standard revenue cycle functions. We believe substantially more testing and piloting of these solutions, particularly in real-world health care settings is necessary not only to ensure the maturity of the IGs, but also to create the data needed to show providers that the investments and workflow changes needed to implement this solution will ultimately result in the rule's projected process improvements. Particularly amidst the extreme financial strain that the ongoing pandemic has placed on many hospitals, the investment of such resources may be limited only where there are recognizable, tangible and substantial benefits. Ensuring sufficient provider participation in testing the standards is crucial to evaluate their viability and readiness for widespread implementation across payers and providers. **Accordingly, we strongly urge CMS to conduct demonstrations prior to the Jan. 1, 2026, implementation date.**

The proposed IGs are at the standard for trial use (STU) ballot level and are not yet normative (i.e., finalized). According to HL7, an STU ballot classification "is used to vet content that is deemed 'ready to implement' by a sponsoring work group, but where there has not yet been significant implementation experience."[17] In fact, the recommended IGs currently are undergoing ballot reconciliation and are actively being revised.[18, 19, 20] While we support this ongoing technology development to ensure that the technology can meet industry need, it is important that **any solution be fully developed and tested prior to wide scale industry rollout and required usage.** This process should include careful consideration as to the transactions' scalability, privacy guardrails and necessity of access to the transmitted health information and ability to complete administrative tasks in a real-world setting, rather than a controlled environment such as an HL7 Connectathon.

Robust pilot testing prior to implementation would not only ensure that the transaction is truly ready for real-world usage, but also provide important data on the beneficial improvements achieved through usage of the transaction (e.g., reduced delays, elimination of administrative burden). We strongly encourage CMS to play an active role and observe the continued development and testing of the Da Vinci IGs. **We recommend that CMS review and release formal assessment of the technology development no later than July 1, 2024, (18 months prior to the scheduled**

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[17] HL7, HL7 Balloting, Available at: https://confluence.hl7.org/display/HL7/HL7+Balloting
[18] HL7, Coverage Requirements Discovery (CRD), Available at: https://confluence.hl7.org/pages/viewpage.action?pageId=21857602
[19] HL7, Documentation Templates and Payer Rules (DTR), Available at: https://confluence.hl7.org/pages/viewpage.action?pageId=21857604
[20] HL7, Prior Authorization Support (PAS), Available at: https://confluence.hl7.org/pages/viewpage.action?pageId=42993876

implementation date) to ensure that the technology is sufficiently developed to accomplish the projected improvements and can be implemented in confidence by providers. Proof of adequate return on investment inevitably will be critical to convincing providers and plans to undertake the significant technology investments and workflow adjustments needed to utilize the IGs.

Coverage Requirements Discovery (CRD) and Documents, Templates and Rules (DTR)

We applaud CMS for recognizing the difficulty that providers often face when trying to determine the potential prior authorization requirements for a particular item or service. As a result of the significant variability between health plans' prior authorization services lists and approval criteria, providers often are uncertain as to whether a particular recommended patient service requires prior authorization, and which documents the plan requires for approval. Currently, obtaining this information requires significant provider and staff time and hassle spent combing through a myriad of payer websites and policy manuals.

We believe that EHR-based technology that allows providers to determine prior authorization requirements at the point of care will significantly improve the delivery of care, reducing much of the ambiguity associated with prior authorization. And while we strongly support the PARDD API automating the compilation of necessary data to populate the prior authorization transactions, it is imperative that providers are made aware of the medical necessity criteria applied to a specific prior authorization request.

Furthermore, medical necessity criteria transparency is critical because, as an April 2022 HHS-OIG report found, MA organizations often administer proprietary medical necessity criteria that is inconsistent with Medicare coverage rules.[21] Inconsistent and overly restrictive plan criteria frequently prevents or delays beneficiaries from receiving medically necessary care to which they are entitled. Too frequently this leads to providers being forced to engage in lengthy and resource-intense appeals processes before MA organizations properly apply applicable criteria, as highlighted by a September 2018 HHS-OIG report.[22] That report found that MA organizations overturned more than 75% of their own medical necessity denials when appealed. Unfortunately for patients and providers, it is often not practical to delay care while appeals are adjudicated. Therefore, in order to ensure that patients receive necessary care in a

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[21] U.S. Department of Health and Human Services Office of Inspector General. "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care," Available at: https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf
[22] U.S. Department of Health and Human Services Office of Inspector General. "Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns about Service and Payment Denials," Available at: https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf

timely manner, the AHA has repeatedly pressed CMS to prevent plans from using the appeals process to correct noncompliance with CMS medical necessity rules, and we reiterate those concerns once again.[23, 24] We believe alerting providers of the medical necessity criteria applied to a prior authorization request will advance transparency, serve as a guardrail to ensure medical necessity criteria is appropriate and lead to more timely care for patients.

Moreover, while the DTR IG can incorporate the necessary connections for easily transmitting information, we have some concerns about the specific access to provider systems granted under the guides. Boundaries are necessary to ensure that payers only are accessing the patient information that is necessary to process a particular prior authorization request. For example, the April 2022 HHS-OIG report found that MA organizations denied prior authorization requests for medically necessary services when providers did not respond to requests for unnecessary documentation.[25] Insurers must be prohibited from making such requests for unnecessary documentation through DTR. **We encourage CMS to ensure that payer access to patient information is limited only to the specific information needed for adjudication of a prior authorization request rather than unfettered access.**

Prior Authorization Support (PAS) and the X12 278

As part of the PARDD API, CMS recommends that plans implement the FHIR-based PAS IG that gives providers the capability to send prior authorization requests and receive responses electronically within their existing workflow. As stated, we strongly support the use of EHR technology for the submission and processing of prior authorizations, as it empowers clinicians to utilize this information during treatment planning and creates the potential for meaningful, real-time access to this data.

However, HIPAA currently requires the PAS FHIR Bundle to be translated into and out of the X12 278 transaction, thereby requiring an intermediary between the provider's and the payer's FHIR-based systems. While we appreciate that the X12 standard ensures that providers are entitled to the protections afforded by the HIPAA regulations, the translation into and out of the 278 for the sole purpose of maintaining HIPAA compliance provides no value to patients, payers or providers. Rather, the translation of FHIR data into and out of the X12 278 will likely require the use of clearinghouses

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[23] American Hospital Association, Re: CMS-4203-NC, Medicare Program; Request for Information on Medicare, Available at: https://www.aha.org/system/files/media/file/2022/08/aha-comments-on-cms-request-for-information-re-the-medicare-advantage-program-letter-8-31-22.pdf

[24] American Hospital Association, Re: CMS 4201-P, Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Program, Available at: https://www.aha.org/system/files/media/file/2023/02/aha-comments-on-the-cms-proposed-rule-for-policy-and-technical-changes-to-the-medicare-advantage-program-in-cy-2024-letter-2-13-23.pdf

[25] U.S. Department of Health and Human Services Office of Inspector General. "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care," Available at: https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf

serving as middlemen in the process, which runs contrary to HIPAA's administrative simplification goals and undermines the provider and industry savings achieved in the process. In addition, translating the PAS FHIR Bundle into and out of the X12 278 only serves to increase the potential for processing errors. In fact, the mapping between FHIR and the X12 278 is incomplete and has not been properly vetted or tested, creating an unnecessary technical hurdle. Moreover, the PAS IG is written in such a way that it enables a FHIR–to-FHIR transaction without unnecessary translation that can degrade the functionality of the transaction and the ability to complete the prior authorization transaction. This is illustrated by the Da Vinci HIPAA Exception that was approved by CMS through July 14, 2024, for a number of payers and their trading partners.[26]

As a result, we encourage CMS to create a pathway toward a streamlined, consistent process for plans and providers to exchange these transactions directly without the need for clearinghouse translation. **Accordingly, we urge CMS to explore utilization of the HHS Secretary's authority to replace the X12 278 HIPAA standard with the FHIR-based translation detailed in this rule.**

PATIENT ACCESS API

CMS proposes to require affected plans to include, as part of the Patient Access API established in the Interoperability and Patient Access final rule, information about the patient's pending, active, denied and expired prior authorization decisions to ensure they have a better understanding of the prior authorization process and its impact on their care. We agree that a program that increases the transparency surrounding the prior authorization process would be beneficial for patients, as these utilization management policies frequently have a significant impact on their care.

The AHA supports patients utilizing the Patient Access API to access the supporting documentation used for a particular prior authorization request to gain visibility into what the payer is evaluating and better understand the payer's clinical criteria. However, CMS also envisions patients utilizing the Patient Access API to identify missing information and potentially help providers deliver information to payers to facilitate a successful prior authorization request. Although we strongly support empowering patients to better understand and engage in their care, patient involvement should not be expected or required. Many of the procedures subject to prior authorization are complex, major, medical processes (e.g., cancer treatments, advanced imaging, surgeries). At such a time, patients are likely to have significant health concerns and may not wish to be burdened with administrative tasks, especially those as complex as prior authorization and medical necessity determinations. We recommend that the regulation be clarified to ensure that patient involvement is completely voluntary.

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[26] HL7, Da Vinci HIPAA Exemption, Available at: https://confluence.hl7.org/display/DVP/Da+Vinci+HIPAA+Exception

We strongly agree with CMS that one of the most important aspects of making health data accessible to patients is to protect the privacy and security of patient health information. This is particularly important once a patient's data is received by a non-HIPAA covered entity third-party application. We applaud CMS' commitment to ensuring patient privacy and security is protected, and we encourage CMS to continue exploring ways to promote interoperability while protecting patient privacy.

PROVIDER ACCESS API

The proposal also establishes the Provider Access API, a FHIR-based platform that allows a provider to access patients' claims and encounter data, clinical data maintained by the plan, and information on pending and active prior authorization decisions. We strongly support these provisions, which could help providers better manage a patient's care, enable more informed decision-making and potentially prevent the provision or ordering of duplicative services.

PAYER-TO-PAYER API

CMS is proposing to rescind the Interoperability and Patient Access final rule payer-to-payer data exchange policy and instead proposing a new policy that would require impacted payers to implement and maintain a payer-to-payer API. The payer-to-payer API would use the FHIR standard, as payers have already devoted the resources to stand up a FHIR API infrastructure when they implemented the Patient Access API, which could be adapted for expanded interoperability use cases. Leveraging this API, impacted payers would be required to exchange patient health information with a patient's subsequent health plan, as well as information about pending, active, denied and expired prior authorizations thereby enabling the maintenance of a more comprehensive health record with the patient's active plan.

Due to the impact that prior authorizations often have on patient care, we commend CMS for requiring this information to be exchanged with subsequent plans at a patient's request. Particularly for patients battling chronic conditions and those whose coverage changes during treatment, prior authorizations can disrupt medical care for which medical necessity has been established already. To ensure that these patients do not experience delays or negative outcomes resulting from prior authorization, we urge that CMS require subsequent plans to honor a previous payer's prior authorization approval for at least 60 days.

REASON FOR DENIAL OF PRIOR AUTHORIZATION

The AHA appreciates CMS' proposal to require impacted payers to provide a specific reason for denied prior authorization decisions regardless of the method used to send the prior authorization request. The proposal acknowledges the importance of sufficient information in prior authorization denials, as providers must understand why a request is

denied so that they can either resubmit it with updated information, identify treatment alternatives, appeal the decision or communicate the decision to their patient. Under the terms of the proposal, payers would be required to provide a specific reason a prior authorization request is denied, such as indicating necessary documentation was not provided, the services are not determined to be medically necessary, or the patient has exceeded limits on allowable care for a given type of item or service. This information is necessary for a provider to determine their best next steps to support getting the patient the care needed in a timely manner.

This proposal would help address a significant problem in the field, as providers and patients are often left without adequate explanation as to a denied prior authorization request. We support this proposal and encourage CMS to establish enforcement mechanisms to ensure that plans are compliant with its requirements.

TIMELINESS STANDARDS

CMS proposes to require impacted payers to deliver prior authorization decisions for health care items or services no later than seven calendar days after the date of the receipt of the request for a standard determination and 72 hours following the receipt of the request for an expedited determination. While we appreciate the objective of making prior authorization decisions timelier, these timeframes are unreasonably lenient.

Unlike other transactions between a provider and health plan, prior authorization has a direct impact on patient care. A prior authorization request is often the final step between a patient and the initiation of their care, making expeditious processing of such transactions extremely important. One challenge to timely adjudication of requests is the lack of an efficient and standard method of delivering the clinical documents necessary to process prior authorizations, often resorting to slow and non-digitized delivery, such as fax machines and the mailing of documents through the postal service. These inefficiencies can lead to devastating delays spent waiting for authorizations, such as suspected cancer patients anxiously waiting days or even weeks for a diagnostic scan or a psychiatric patient spending extra time in an emergency department while waiting for placement in an appropriate care facility.

The dire need for timely adjudication of prior authorization is particularly evident in post-acute care (PAC) transfers. As CMS knows, institutional PAC care providers, including inpatient rehabilitation hospitals and units, long-term care hospitals, skilled nursing facilities and home health agencies often play a vital role in a patient’s care. PAC providers work to restore function and allow patients to return to their lives after a serious accident or injury, usually after an acute-care hospitalization. However, prior authorization requests to transfer an MA patient to an appropriate PAC facility are often

delayed.[27] For example, an AHA member indicated that a patient with traumatic brain injury was medically ready for discharge but stayed for four additional days in the hospital without access to essential post-acute care because the insurer had not responded to the provider's request to move the patient into a rehabilitation facility.[28] Another AHA member that operates inpatient rehabilitation facilities reports that 11% of their MA referrals take 10 days or longer to resolve. Furthermore, another AHA member reported that, in 2022, over 400 MA patients at its academic medical center had delayed discharges due to insurance issues, the vast majority of which were attributable to prior authorization delays, and the delays amounted to 1,233 avoidable inpatient days.[29] These delays in moving patients has resulted in tremendous strain on general acute care hospital capacity, which has been particularly critical during the COVID-19 pandemic when hospitals have been in desperate need of inpatient beds to care for COVID-19 patients.[30]

The PARDD API proposed under this regulation could effectively eliminate the administrative delays caused by slow delivery of medical documents, as the API boasts the ability to deliver clinical information in real-time. As stated in the PAS IG, "the payer system is expected to immediately generate an automated response. Ideally, this will represent a final decision on the prior authorization request."[31] As a result of having the clinical information delivered in such an expeditious manner, health plans should have the capability to determine whether the provider has met their established medical necessity threshold in a much timelier manner. Patients should not be forced to wait to receive care for longer than is necessary. Additionally, it is critical that "pended" prior authorization decisions are not considered sufficient to satisfy decision timeframes. **We recommend that plans be required to deliver prior authorization responses within 72 hours for standard, non-urgent services and 24 hours for urgent services for transactions utilizing the FHIR technology established under this rule.**

The proposed rule continues to allow plans to extend prior authorization deadlines by up to 14 days if the plan determines that the submitted medical documentation is insufficient to make a determination. We find this to be inappropriate, particularly considering the PARDD API capabilities. If a provider utilizes the FHIR transactions required in the regulation, their EHR system should have the information necessary for prior authorization decision-making to occur. Absent a provider failing to deliver some of the informational requests included in the API processes, plans should not be permitted to extend a prior authorization determination. In addition, regardless of how a prior

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[27] American Hospital Association, Re: CMS-4203-NC, Medicare Program; Request for Information on Medicare, Available at: https://www.aha.org/system/files/media/file/2022/08/aha-comments-on-cms-request-for-information-re-the-medicare-advantage-program-letter-8-31-22.pdf
[28] Example provided by an AHA member hospital.
[29] Example provided by an AHA member hospital.
[30] Example provided by an AHA member hospital.
[31] HL7, Da Vinci Prior Authorization Support (PAS), Available at: http://hl7.org/fhir/us/davinci-pas/2022May/specification.html

authorization is requested, permitting additional time for supplementary information may incentivize a plan to change documentation requirements after the request was made or make unnecessary documentation requests to excuse a delay in approving care.

Furthermore, we disagree with the proposal's timeliness standards not being applicable to qualified health plan (QHP) issuers on the Federally-Facilitated Exchanges. Patients on these plans should be entitled to the same protections as the others covered under this regulation. These plans should not be allowed to enact prior authorization policies that exceed the timeframes established in the proposed rule. Such discrepancy unnecessarily limits the scope of this regulation and reduces its ability to improve care delays for these patients.

Requiring near real-time responses to electronic prior authorization requests via the PARDD API will benefit providers and incentivize them to adopt the necessary technology.

PRIOR AUTHORIZATION DATA REPORTING REQUIREMENTS

The AHA strongly supports CMS' proposal to require plans to report metrics on their prior authorization processes. Specifically, we believe that by requiring plans to report the percentage of prior authorization requests approved, denied and denials overturned on appeal, and the average time between submission and determination, the rule promotes much-needed transparencies and the opportunity to build accountability. While there is a significant amount of research and reporting that establishes the burden that inefficient prior authorizations have on patients and providers, there are limited resources available for determining particularly problematic plans.

Plan prior authorization metrics buried on individual plan sites add little to no benefit to patients. Instead, we believe it **is important that CMS directly collect these data and make them publicly available on a single website, like other performance measures**.

Further, we encourage CMS to create mechanisms whereby this data is used to guide oversight and enforcement activities. This would help ensure compliance with CMS rules, which have direct impacts on patient access to care and outcomes. Accordingly, **we recommend that CMS regularly audit a sample of plan denials and timeframes, as well as use the data to target potentially problematic plans.** Without this level of detailed auditing, there will be ample opportunity for certain health plans to continue circumventing federal rules without detection, rendering the proposed patient transparency efforts and protections ineffective. This will enable meaningful change to take place where it is needed most.

Additionally, we urge CMS to implement this provision prior to the Jan. 1, 2026, implementation date. Though we recognize that it may take time and resources for CMS to collect and aggregate the data and undertake any corresponding enforcement

actions, the requirement that plans publicly report their prior authorization metrics would take few resources to implement and would show improvements before, during and after implementation of the PARDD API. We agree with CMS that year-over-year comparisons could demonstrate positive or negative prior authorization trends, which would be useful information for patients, providers and payers.

GOLD CARDING

The AHA applauds CMS' interest in gold carding as these programs can substantially reduce administrative burdens and cost. Generally, gold carding programs enable providers who have demonstrated consistent adherence to evidence-based guidelines to be granted exemptions from prior authorization requirements. Gold carding programs promote more timely patient access to care, as they would eliminate unnecessary prior authorization adjudication and the corresponding potential seven-day waiting periods that may interrupt care. Furthermore, these programs would still allow health plans to focus prior authorization programs on the providers or services for which they contend the programs are designed — those with less clear care pathways or are new and particularly high cost. As a result, we strongly encourage CMS to explore a method to best implement gold carding programs for the regulation's impacted payers.

As part of this exploration, we recommend that CMS carefully consider how a program could be implemented in a practical manner that would ensure that providers are aware and have confidence in their exemption status. For example, a gold carding process that is overly granular (e.g., exempting a provider only for individual CPT codes) would likely have some issues, as the CPT code may change slightly during care, which could cause reimbursement issues post-care. **We recommend that these programs are applied at the provider level, rather than the service level.**

Additionally, the programs should be designed so that providers are exempt for an established length of time, such as one calendar year. If a program were more fluid, permitting providers to move in and out of gold carding status, providers would not be able to rely upon the exemption as confidently. Furthermore, we would encourage CMS to establish an appropriate rate of approval for providers to reach to achieve "exempt" status. We believe that 85% provider-level approvals would be an appropriate threshold, which would require providers to establish a consistent record of adherence while simultaneously recognizing that a specific patient's medical treatment may occasionally warrant prescribing care that does not align fully with a plan's notion of medical necessity.

INCENTIVIZING PROVIDER USE OF ELECTRONIC PRIOR AUTHORIZATION

CMS requests information regarding ways to incentivize provider adoption of the PARDD API. Hospitals and health systems are eager to adopt and use technology that improves the safety, quality and efficiency of care. Generally, in instances where

adoption is slower, it is due to excessive financial cost or workforce burden that cannot be borne by the provider at that time.

CMS proposes using the Promoting Interoperability Program to create an even stronger incentive for providers to use the PAARD API. Specifically, CMS would add a new measure, called Electronic Prior Authorization, to the hospital Medicare Promoting Interoperability Program and the promoting interoperability category of the Merit-based Incentive Payment System (MIPS). Eligible hospitals and clinicians would be required to report whether they submitted at least one prior authorization request using the PARDD API beginning in 2026 with scoring starting at a future date.

While the AHA understands CMS' desire to incentivize the use of the PARDD API, we believe utilizing a heavy-handed regulatory lever, such as the hospital Promoting Interoperability Program, is unnecessary. Furthermore, the proposed rule lacks detail about how the scoring of this measure would be tied to the broader promoting interoperability program. Such detail would be critical in evaluating the suitability of this measure for inclusion in the program. Lastly, given the already significant draws on limited IT resources for hospitals, health systems and clinicians, the burden of reporting the measure likely would outweigh the benefit of its use.

Instead of establishing a new Promoting Interoperability Program measure, we encourage CMS to first explore whether it can obtain data from payers on provider participation in the PAARD API, as they would have this information easily accessible. If CMS is intent on moving forward with the inclusion of a measure reflecting provider use of the PARDD API, we encourage CMS to create an attestation-only measure to mitigate provider burden.

Ultimately, provider adoption and use of electronic prior authorization technology will be driven by the value proposition of the technology itself. As mentioned, testing and piloting of these solutions, particularly in real-world health care settings, would create the data needed to show providers that the investments and workflow changes needed to implement this solution will ultimately result in the rule's projected process improvements. Should the PARDD API be built and implemented in such a way that it accomplishes the goals of reducing provider burden, improving prior authorization processing time and enabling more timely access to care for patients, providers will be galvanized to use this transformative technology.

REQUESTS FOR INFORMATION

Request for Information: Accelerating the Adoption of Standards Related to Social Risk Data

The AHA appreciates CMS' interest in the challenges hospitals face in collecting and using social risk data to better serve patients and communities, as well the agency's exploration of whether an acceleration of social risk data standards may be helpful.

America's hospitals and health systems are deeply committed to identifying and eliminating disparities in health outcomes. Social risk factors can either facilitate or impede a person's ability to maintain or return to a state of health. This makes the availability and use of reliable, relevant social risk data important to improving health equity.

At the same time, we caution CMS against mandating the use standards for collecting and transmitting these data prematurely. As described below, hospitals and health systems have implemented a range of mechanisms to capture social risk data that align with the needs of the patients and communities they serve, all of which are resource intensive. While greater data standardization clearly could have important benefits, a precipitous mandate to use certain standards could also be disruptive to the field. Ultimately, the goal of social risk data standards goes well beyond data capture; rather, it is to reduce health inequities and improve care for all. For that reason, we would urge CMS to adopt only those standards that receive extensive input from the field, directly relevant to improving disparities and flexible enough to meet the varied capabilities and needs of hospitals and communities.

Capturing and Using Social Risk Data. **Collecting social risk data, incorporating it into the clinical record and using it to shape the care plan is a complex and dynamic process.** The AHA's 2019 report on screening for social needs describes in depth the processes and challenges that hospitals face with implementing social need screening tools.[32] As the report shows, hospitals and health systems face an array of choices in determining at what point of care to capture the information. They could use admission interviews conducted by an intake nurse. They could capture the information during outpatient visits using clinicians or other non-clinical members of the care team. They could have patients fill out paper forms or use electronic mechanisms. In some cases, more sensitive information (e.g., issues around violence or abuse) may be best captured through conversations with a clinician the patient trusts rather than through forms. Hospitals generally make their choice of data collection approach based on the needs of their patient population and their own processes.

The initial capture of social risk factor data is a foundational step, but it is just the beginning. It also is important to document the data in clinical and administrative records in ways that helps hospitals not only track broader trends across their patient populations, but also provide information relevant to clinicians at the point of care. Hospitals and health systems are continuing to explore multiple mechanisms of optimizing sharing of social risk data across settings. For example, some hospitals are capturing social determinants data using ICD-10 CM codes related to social determinants of health (i.e., "Z codes"). The codes help hospitals document non-medical social risk factors that may influence a patient's health status, including education and

[32] American Hospital Association, "Screening for Social Needs: Guiding Care Teams to Engage Patients," Available at: https://www.aha.org/system/files/media/file/2019/09/screening-for-social-needs-tool-value-initiative-rev-9-26-2019.pdf

literacy, employment, housing, lack of adequate food or water or occupational exposure to risk factors like dust, radiation or toxic agents. The codes can facilitate population-level trends analysis, and social determinant flags in EHR systems. That is why the AHA's Coding Clinic has provided resources to hospitals to help increase the utilization of these codes.[33] At the same time, given the continued emergence of multiple approaches to capturing and exchanging social risk data, we would not recommend that the reporting of Z codes be mandated at this time. Standards and best practices around the capture and reporting of social determinant data are rapidly evolving, making it important to continue to provide hospitals with the flexibility to adopt approaches to capturing data that best align with their care processes and technical capabilities

EHR Standards Challenges. Many hospitals also have pointed to EHRs as a potential mechanism for not only capturing social risk factor data in a more standardized fashion, but also making it accessible to clinicians at the point of care. This is especially true given that EHRs may be able to catalog more rapidly the inevitable changes to patients' specific social risk factors over time.

The EHR certification standards developed by the ONC hold promise for promoting greater standardization of social risk factor data in EHRs. However, significant gaps in standards remain. ONC's EHR certification criteria, test procedures and test tools are used to confirm that an EHR can capture, incorporate and send data in accordance with standard codes. The certification criteria and the testing procedures for some data — such as demographics (as outlined in §170.315(a)(5)) — are specific.

However, for other data in the EHR certification standards — including many related to social risk factors — the testing approach is not prescribed. As a result, social risk data may be collected routinely but perhaps not consistently or in support of a patient population identified as needing particular services. For example, the social, psychological and behavioral data certification criteria (§170.315(a)(15)) requires EHRs to be certified to capture data in eight domains: financial resource strain, education, stress, depression, physical activity, alcohol use, social connection and isolation, and exposure to violence. Certified EHRs are required to capture whether the individual provides a level of response to each domain but are not certified to indicate if the individual declined to respond to the question. The criteria also permit EHRs to capture information in text fields rather than structured codes. Furthermore, the testing approach for this certification criteria is self-declaration.

Additional work is needed to standardize the data collected in electronic form, test EHRs to confirm the consistent implementation of the standards, and crosswalk the standard data to social risk factor measures or well-established social risk factor

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[33] American Hospital Association, "ICD-10-CM Coding for Social Determinants of Health," Available at: https://www.aha.org/system/files/2018-04/value-initiative-icd-10-code-social-determinants-of-health.pdf

screening tools. **The AHA recommends CMS collaborate with ONC, providers, and EHR and health IT vendors to develop or refine standards, implementation requirements and guidelines to support the effective capture and use of social risk data in EHRs.**

The successful development of these EHR standards could enable further development of tools to help identify and address social risk factors at the patient and population level. At the patient level, a positive screen for a social risk factor could provide a clinical decision support tool linking clinicians to internal or community partner resources that may benefit a particular patient. At the population level, hospitals may be able to use mapping and visualization tools to help illuminate geographic areas of communities that are particularly at risk, or better detect associations between social risk factors and health outcomes. This could better target interventions and hospital population health strategies.

Request for Information: Improving the Exchange of Information in Medicare Fee for Service

The AHA appreciates CMS' interest in facilitating electronic data exchange between and among providers, suppliers, and patients in the fee-for-service (FFS) Medicare program. We share CMS' belief that the use of communication methods such as fax machines and the U.S. Postal Service is laborious, and we welcome solutions that enable more efficient exchange of clinical information. As we detail throughout our comments, for providers to participate in health IT data exchange, CMS should push all payers to adopt a standard method of exchanging this data that is accepted by all of the various payers with whom a hospital interacts. We believe that electronic health information sharing plays a critical role in improving care quality and the patient experience.

The advancement of automation to promote interoperability offers the potential to reduce provider burden and accelerate the delivery of care. However, the costs associated with setting up and maintaining new interfaces and exchanges are major barriers to the electronic sharing of information. Therefore, we urge CMS to leverage existing technological capabilities, most notably the industry investment in EHRs. We encourage CMS to identify what can be accomplished using certified EHR technology that providers already are required to adopt for participation in federal programs, including FFS Medicare. Moreover, we encourage ONC to prioritize CMS' proposed technical changes and make changes part of its certification program to ensure that meaningful changes are highly usable in EHR programs and enable all health care stakeholders to realize their potential.

Request for Information: Advancing Interoperability and Improving Prior Authorization Processes for Maternal Health

The AHA strongly supports policies that would leverage electronic data capabilities to improve maternal health. Specifically, the AHA supports CMS' efforts to improve

maternal health through focusing on improved outcomes and reducing dipartites. We also appreciate this opportunity to share concerns our member hospitals have shared with us regarding how certain prior authorization practices create barriers to care and reduce access to services. As the RFI notes, several health plans limit pregnant patients' access to imaging services such as ultrasound without a high-risk diagnosis. We have heard specifically from our member hospitals that serve on AHA's Maternal and Child Health Committee that such prior authorization practices limit a provider's ability to monitor a patient's pregnancy. Delays in access to care for pregnancy testing, imaging or other treatment services caused by utilization management practices can jeopardize the health of the mother and baby. Therefore, there should be special considerations for prior authorizations for maternal health care that apply to the continuum care for the pregnant patient — prenatal, perinatal and postnatal periods — to ensure the health of the mother as well as the baby.

In addition, the RFI asks for Medicaid-related experiences with prior authorization and whether prior authorizations should carry over from one payer to another. According to various member hospitals, it is extremely onerous to switch plans when circumstances change in states where there are multiple Medicaid managed care plans. Differing plans with varying coverage criteria and restrictions can pose a risk to pregnant women, especially those in their third trimester or those with higher-risk pregnancies and complications. This coverage issue is particularly challenging in rural areas where pregnant women may need to seek needed care across state lines. Accordingly, we urge CMS to require that prior authorizations carry over from one payer to another when a patient changes payers during pregnancy.

CONCLUSION

We thank you for the opportunity to comment on these important topics. We particularly appreciate CMS' thoughtful proposals to alleviate provider burden and improve patient care and access and appreciate your consideration of our recommendations. **We urge CMS to expeditiously finalize the Advancing Interoperability and Improving Prior Authorization Processes proposed rule.** Please contact me if you have any questions, or feel free to have a member of your team contact Andrea Preisler, AHA's senior associate director for administrative simplification policy, at apreisler@aha.org.

Sincerely,

/s/

Ashley Thompson
Senior Vice President
Public Policy Analysis and Development